

## **DEPARTMENT OF HEALTH**

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## Hawai'i Department of Health issues cease & desist order, \$58,000 penalty to NextHealth for conducting unauthorized COVID-19 testing

HONOLULU – The Hawai'i Department of Health (DOH) has ordered NextHealth to immediately cease and desist performing COVID-19 tests in the State of Hawai'i without a license, permit or written approval. DOH also levied a \$58,000 administrative penalty.

NextHealth performed COVID-19 testing beginning from October 11, 2021 at the Four Seasons Resort Maui in Wailea located at 3900 Wailea Alanui Drive, Kihei, Hawai'i. Approximately 982 patients were tested during that time.

Laboratories are regulated under the authority of federal and state statutes, which ensure providers operating in Hawai'i deliver quality services that meet federal and state standards.

"Testing is critically important as we continue to navigate through this pandemic. Residents need to be sure testing is done accurately, appropriately, and safely," **said Health Director Dr. Elizabeth Char, FACEP**.

After learning that NextHealth was performing COVID-19 tests in Hawai'i, DOH contacted NextHealth regarding operating a clinical laboratory without proper permits. The DOH Office of Health Care Assurance (OHCA) then conducted an onsite investigation and determined that NextHealth was operating without a CLIA Certificate of Waiver and a State of Hawaii Clinical Laboratory Class I Permit as required under 42 C.F.R. Part 493 Subpart A and 11-110.1-6(a) Hawaii Administrative Rules (HAR) for the establishment of a clinical laboratory as required by law.

NextHealth is ordered to immediately:

- Cease and desist operating a Class I Clinical Laboratory at the Four Seasons Resort Maui and any other clinical laboratory locations within the State of Hawai'i;
- Pay an administrative penalty totaling \$58,000;
- Notify DOH OHCA in writing of all clinical laboratories operated by NextHealth within the State of Hawai'i and confirm the date operations ceased; and
- Not open or operate any clinical laboratory in the State of Hawai'i without a valid state certificate, permit or obtaining prior written approval from DOH OHCA.

Individuals who received testing through NextHealth should contact their physician for guidance on whether they should seek testing through another provider.

Click here to read the full Order to Cease and Desist.

For information on COVID-19 testing visit <a href="https://example.com/testing">HawaiiCOVID19.com/testing</a>.